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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/281,990

Applicant(s)

ELLING ET AL.

Examiner

Monika B. Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 39-62 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 22-38, 63-66, and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 29 March 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.

Application from the International Preliminary Examination Report (IPER) is attached.
See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 sheets
4. ☐ Interview Summary (PTO-413) Paper No(s) _____
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Other Attachment PTO-948

DETAILED ACTION

Restriction Election

Claims 1-21, 39-62, and 67, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant's election of Group III (containing claims 22-38, 63-66, and 68), in Paper No. 8, filed on April 25, 2001, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-38, 63-66, and 68, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23, 31-32, 63-66, and 68, lack clarity in the stepwise manner in which to execute the claimed methods, computer readable mediums, and processing systems. The steps the performance of step (a) - the last step (c) of each of the claims states an output of data that has not yet been "entered". Therefore claims 22-23, 31-32, 63-66, and 68, are vague and

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indefinite. Claims 24-30 and 33-38, are rendered indefinite due to their dependency from claims 23 and 32 (respectively), indefinite claims.

Claims 22-38 are vague and indefinite due to the disparity between that which the steps design and that which the preamble sets out to accomplish. The steps do not clearly set forth the actual production of a pharmacophore, but a method of designing a pharmacophore. Therefore the language used in the preamble does not clearly point out the methods claimed in claims 22-38.

Claims 22, 23, 31, and 32, are vague and indefinite to the metes and bounds of the "pharmacophore" (line 1) in the preamble of the claimed methods. The extent of what the pharmacophore is based upon in terms of the instant invention are unclear; for example, basis on a chemical activity that would result in an established pharmacophoric activity. Claims 24-30 and 33-38, are rendered indefinite due to their dependency from claims 23 and 32 (respectively), indefinite claims.

Claim 22 and 23 are vague and indefinite in the term "cooperatively" (line 5 and 6, respectively). The language used creates conflicting information: molecules being grouped together based upon common individual structural features, are then stated to be cooperating with each other to represent a particular activity. It is confusing if the molecules placed separately again would display this activity or not. Due to the lack of clarity, claim 22 is rendered indefinite

group contains at least a predetermined percent of molecules having said particular activity characteristic" The selected group claimed was already clustered together by the parameters for clustering being the said particular activity. Therefore the predetermined percent of molecules

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within the "selected group" contradicts the earlier stated parameters of the computerized grouping of claim 24 and 33, lines 6-7.

The language of claim 30 is unclear. The meaning of the statement "along a dimension related to the activity characteristics", as seen in line 4, lacks any clarity as to what or which dimension is being considered; for example, 2nd dimension, 3rd dimension, or the actual size in dimensions. The meaning of "a dimension" as any singular item on the complex issue of molecular structural features or activity characteristics is unclear.

The language of claims 23 and 32 is unclear. The meaning of the statement "based at least in part on a measure of how much...in defining the discriminating features", as seen in lines 10-11, lacks any clarity as to what measurement is being considered. The meaning of "a measure of how much" as a mathematical calculation on the complex issue of molecular structural features or activity characteristics is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on

Claims 22-28, 03-06, and 08, are rejected under 35 U.S.C. 102(b) as being anticipated by Hibert et al. (*J. Med. Chem.*, 1988).

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Hibert et al. teaches a computerized method of producing a pharmacophore based on structural features and activity characteristics, or selectivity, as recited in claims 22, 23, 31, and 32, in the abstract. One page 1088 (2nd column, (ii)), Hibert et al. demonstrates the establishment of molecular descriptions based on structural features in the detailing of Scheme I; as seen in line 3 in both claims 22 and 23, and line 4 of claims 31 and 32. The reference demonstrates in the same place, the molecular group selection based on similar descriptions as detailed in Scheme II; as seen in line 5 of claims 22 and 23, and line 6 of claims 31 and 32. The reference teaches on page 1089 (1st column), stated the establishment of a pharmacophore based upon the "commonalities in this group of compounds" (p. 1089, line 8) as seen in claim 22, line 7. As the commonalities are compared two basic structural parameters we stated necessary (p. 1089, end of column 1), thus anticipating new descriptor establishment after molecular grouping of claim 31, line 8 and claim 32, line 13. The output of data as seen in claims 22, 23, 31, and 32 is displayed upon the computer screen as models of the pharmacophore or index tables as scene in Table II (p. 1088). For example, Table III (p.1091) displays the output of data of grouped compounds indicative of a pharmacophores as recited in claim 22, line 9; Figure 2 (p.1089) displays the output of a basic feature of a pharmacophore as recited in claim 23 line 11; and Figure 1 (p.1089) displays the output of a model representing the two other basic structural parameters of a possible pharmacophore as recited in claims 31 and 32. Therefore, the independent claims 22, 23, 31, and 32, are anticipated by Hibert et al. As such, claims drawn to Hibert et al.

Claim 24 is taught by the reference on page 1087, in the group created for the experiments contained molecules having a particular activity characteristic, such as binding

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affinity to a particular receptor. The predetermined number of molecules having a particular activity characteristic as stated in claim 25, is demonstrated by the reference selecting the molecules based on their affinity to a specific receptor. Since all of these molecules held some affinity to binding to the receptor, the reference teaches a selected group of molecules to contain 100 percent of the stated particular activity characteristic as described in claim 26. The clustering of the data described in claim 27, is demonstrated by the table in the Supplementary Material, pages 32-34. Thus claims 24-27 are anticipated by Hibert et al.

Claims 63-66 and 68, are anticipated by Hibert et al. since the described computerized method inherently requires the computer readable mediums of claims 63 and 65, as well as the processing systems of 64, 66, and 68.

No claim is allowed.

Information Disclosure Consideration

The information disclosure statement filed July 12, 1999, has a few publications that have not been considered due to lack of publication date. The date of a computer print-out does not qualify as the publication date. In addition, the "received date" of Barnard et al. (June 27, 1997) also does not qualify as a publication date. Therefore Barnard et al. can not be fully considered due to lack of publication date.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 05-01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 09, March,

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21, 2001. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Monika B. Sheinberg
Patent Examiner
Art Unit 1631

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11/11/01